

Patient package insert according to Pharmacists' Regulations (Preparations), 1986

This medicine can be sold with a physician's prescription only

## Rivastigmine Patch Dexcel 4.6mg /24h

## Rivastigmine Patch Dexcel 9.5mg /24h

### Transdermal patch

#### Each patch contains:

**Rivastigmine Patch Dexcel 4.6mg/24h:** Each transdermal patch is 4.6 cm<sup>2</sup> and contains 6.9 mg of rivastigmine. The release rate is 4.6 mg in 24 hours.

**Rivastigmine Patch Dexcel 9.5mg/24h:** Each transdermal patch is 9.2 cm<sup>2</sup> and contains 13.8 mg of rivastigmine. The release rate is 9.5 mg in 24 hours.

Inactive ingredients— please see section 6 "Additional information".

**Read this entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours. The medicine is intended for use in adults over the age of 18.

### 1. What is the medicine used for?

For the treatment of patients with mild to moderately severe Alzheimer's dementia. In patients with Alzheimer's dementia, certain nerve cells die in the brain, resulting in low levels of the neurotransmitter acetylcholine (a substance that allows nerve cells to communicate with each other). Rivastigmine works by blocking the enzymes that break down acetylcholine: acetylcholinesterase and butyrylcholinesterase. By blocking these enzymes, rivastigmine allows levels of acetylcholine to be increased in the brain and helps to reduce the symptoms of Alzheimer's disease.

**Therapeutic group:** cholinesterase inhibitors

### 2. Before you take the medicine

#### Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (rivastigmine) or to any of the additional ingredients that this medicine contains (see section 6).
- You have ever had an allergic reaction to a similar type of medicine (carbamate derivatives).
- You have a skin reaction spreading beyond the patch size, if there is a more intense local reaction (such as blisters, increasing skin inflammation, swelling) and if it does not improve within 48 hours after removal of the transdermal patch.

If this applies to you, tell your doctor and do not apply **Rivastigmine Patch Dexcel**.

#### Special warnings regarding the use of this medicine

##### Before treatment with Rivastigmine Patch Dexcel, tell your doctor if:

- You have, or have ever had, an irregular or slow heartbeat.
  - You have, or have ever had, an active stomach ulcer.
  - You have, or have ever had, difficulties in passing urine.
  - You have, or have ever had, seizures.
  - You have, or have ever had, asthma or a severe respiratory disease.
  - You suffer from trembling.
  - You have a low body weight.
  - You have gastrointestinal reactions such as feeling sick (nausea), being sick (vomiting) and diarrhoea. You may become dehydrated (losing too much fluid) if vomiting or diarrhoea are prolonged.
  - You have impaired liver function.
- If any of these apply to you, your doctor may need to monitor you more closely while you are on this medicine.

If you have not applied **Rivastigmine Patch Dexcel** for more than three days, do not apply the next one before you have talked to your doctor.

#### Children and adolescents

Rivastigmine is not intended for use in children and adolescents under 18 years of age.

#### Other medicines and Rivastigmine

**If you are taking, or if you have recently taken any other medicines, including non-prescription drugs and dietary supplements, please tell your doctor or pharmacist.** Especially if you are taking:

- Rivastigmine might interfere with anticholinergic medicines some of which are medicines used to relieve stomach cramps or spasms (e.g. dicyclomine), to treat Parkinson's disease (e.g. amantadine) or to prevent motion sickness (e.g. diphenhydramine, scopolamine, or meclizine).
- **Rivastigmine Patch Dexcel** should not be given at the same time as metoclopramide (a medicine used to relieve or prevent nausea and vomiting). Taking the two medicines together could cause problems such as stiff limbs and trembling hands.
- If you have to undergo surgery whilst using **Rivastigmine Patch Dexcel**, tell your doctor that you are using them because **Rivastigmine Patch Dexcel** may exaggerate the effects of some muscle relaxants during anaesthesia.
- Caution when **Rivastigmine Patch Dexcel** is given together with beta-blockers (medicines such as atenolol used to treat hypertension, angina, and other heart conditions). Taking the two medicines together could cause problems such as slowing of the heartbeat (bradycardia) leading to fainting or loss of consciousness.

#### Use of this medicine with food

Food or beverages have no effect on **Rivastigmine Patch Dexcel**.

#### Use of this medicine with alcohol consumption

Alcohol consumption has no effect on **Rivastigmine Patch Dexcel**.

#### Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If you are pregnant, the benefits of using rivastigmine must be assessed against the possible effects on your unborn child.

Rivastigmine should not be used during pregnancy unless clearly necessary.

You should not breast-feed during treatment with **Rivastigmine Patch Dexcel**.

#### Driving and using machines

Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely. **Rivastigmine Patch Dexcel** may cause fainting or severe confusion.

If you feel faint or confused do not drive, use machines or perform any other tasks that require your attention.

### 3. How to use this medicine?

Always use according to doctor's instructions. You should check with your doctor or pharmacist if you are not sure. The dosage and administration will be determined by the doctor only.

#### IMPORTANT:

- **Take off the previous patch before putting ONE new patch on.**
- **Only one patch per day.**
- **Do not cut the patch into pieces.**
- **Press the patch firmly in place for at least 30 seconds using the palm of the hand.**

#### How to start treatment?

Your doctor will tell you which **Rivastigmine Patch Dexcel** is most suitable for you.

- Treatment usually starts with **Rivastigmine Patch Dexcel 4.6 mg/24 h**.
- The recommended usual daily dose is **Rivastigmine Patch Dexcel 9.5 mg/24 h**. If well tolerated, the treating physician may consider increasing the dose to 13.3 mg/24 h (a dose of 13.3 mg/24 hours cannot be reached with **Rivastigmine Patch Dexcel**. In situations where this dose should be used, use other rivastigmine preparations, which have 13.3 mg/24-day dermal patches).
- Only wear one patch at a time and replace the patch with a new one after 24 hours. During the course of the treatment your doctor may adjust the dose to suit your individual needs.

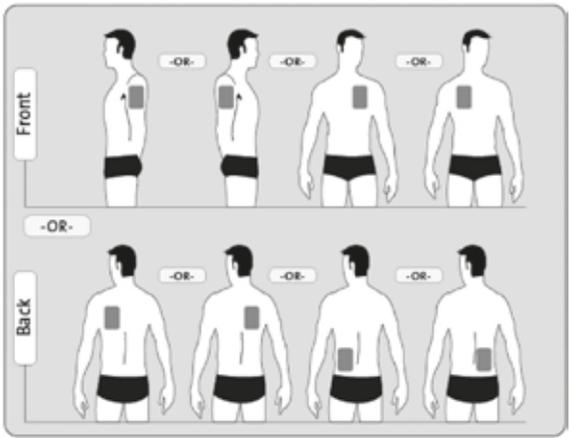
If you have not applied **Rivastigmine Patch Dexcel** for more than three days, do not apply the next one before you have talked to your doctor.

Transdermal patch treatment can be resumed at the same dose if treatment is not interrupted for more than three days. Otherwise your doctor will restart your treatment on **Rivastigmine Patch Dexcel 4.6 mg/24 h**.

#### Where to apply your Rivastigmine Patch Dexcel?

- Before you apply **Rivastigmine Patch Dexcel**, make sure that your skin is clean, dry and hairless, free of any powder, oil, moisturiser or lotion that could keep the patch from sticking to your skin properly, free of cuts, rashes and/or irritations.
- **Carefully remove any existing patch before putting on a new one.** Having multiple patches on your body could expose you to an excessive amount of this medicine which could be potentially dangerous.
- Apply **ONE** patch per day to **ONLY ONE** of the possible locations (described in the photos below):
  - left upper arm or right upper arm
  - left upper chest or right upper chest (avoid breast)
  - left upper back or right upper back
  - left lower back or right lower back

**Every 24 hours take off the previous patch before putting ONE new patch on to ONLY ONE of the following possible locations:**



When changing the patch, you must remove the previous day's patch before you apply the new one to a different location of skin each time (for example on the right side of your body one day, then on the left side the next day, and on your upper body one day, then on your lower body the next day).

Do not apply a new patch to the same skin area twice within 14 days.

#### Do not exceed the recommended dose.

#### How to apply your Rivastigmine Patch Dexcel?

The patches are thin, light brown, plastic patches that stick to the skin. Each patch is sealed in a sachet that protects it until you are ready to put it on. Do not open the sachet or remove a patch until just before you apply it.



Carefully remove the existing patch before putting on a new one.

For patients starting treatment for the first time and for patients restarting after treatment interruption, please begin with the second picture.



Each patch is sealed in its own protective sachet. You should only open the sachet when you are ready to apply the patch. Cut the sachet at both scissors marks, but not further than the indicated line. To open, tear the sachet. Do not cut along the entire length of the sachet in order to avoid damaging of the patch.

Remove the patch from the sachet. Remove the cover sheet from the top, light brown side of the patch and discard it.



A protective liner covers the sticky side of the patch. Peel off one side of the protective liner and do not touch the sticky part of the patch with the fingers.



Put the sticky side of the patch on the upper or lower back or upper arm or chest and then peel off the second side of the protective liner.



Then press the patch firmly in place for **at least 30 seconds** using the palm of the hand to make sure that the edges stick well.

If it helps you, you may write, for example, the day of the week, on the patch with a thin ball point pen.

The patch should be worn continuously until it is time to replace it with a new one. You may wish to experiment with different locations when applying a new patch, to find ones that are most comfortable for you and where clothing will not rub on the patch.

#### How to remove your Rivastigmine Patch Dexcel?

Gently pull at one edge of **Rivastigmine Patch Dexcel** to remove it slowly from the skin. In case the adhesive residue is left over on your skin, gently soak the area with warm water and mild soap or use baby oil to remove it. Alcohol or other dissolving liquids (nail polish remover or other solvents) should not be used.

You should wash your hands with soap and water after removing the patch. In case of contact with eyes or if the eyes become red after handling the patch, rinse immediately with plenty of water and seek medical advice if symptoms do not resolve.

Special instructions on how to discard the patch after use appear in section 5, "How to store the medicine".

#### Can you wear your Rivastigmine Patch Dexcel when you are bathing, swimming, or in the sun?

- Bathing, swimming or showering should not affect the patch. Make sure the patch does not loosen during these activities.
- Do not expose the patch to any external heat sources (e.g. excessive sunlight, saunas, solarium) for long periods of time.

#### What to do if a patch falls off?

If a patch falls off, apply a new one for the rest of the day, then, replace it at the same time as usual the next day.

#### When and for how long to apply your Rivastigmine Patch Dexcel?

- To benefit from treatment, you must apply a new patch every day, preferably at the same time of day.
- Only wear one patch at a time and replace the patch with a new one after 24 hours.

#### If you use more Rivastigmine Patch Dexcel than you should

If you accidentally apply more than one patch, remove all the patches from your skin, then, inform your doctor that you have accidentally applied more than one patch. You may require medical attention. Some people who have accidentally taken too much rivastigmine have experienced feeling sick (nausea), being sick (vomiting), diarrhoea, high blood pressure and hallucinations. Slow heartbeat and fainting may also occur.

**If you forget to use Rivastigmine Patch Dexcel**  
If you find you have forgotten to apply **Rivastigmine Patch Dexcel**, apply one immediately. You may apply the next patch at the usual time the next day. Do not apply two patches to make up for the one that you missed. Continue with the treatment as recommended by your doctor. Even if there is an improvement in your health, do not stop this treatment without consulting your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult your doctor or pharmacist.

### 4. Side effects

Like all medicines, using **Rivastigmine Patch Dexcel** can cause side effects, although not everybody gets them. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

You may have side effects more often when you start your medicine or when your dose is increased. Usually, the side effects will slowly go away as your body gets used to the medicine.

**Take off your Rivastigmine Patch Dexcel and tell your doctor straight away, if you notice any of the following side effects which could become serious:**

#### Common side effects (effects which appear in 1-10 out of 100 users):

- Loss of appetite
- Feeling dizzy
- Feeling agitated or sleepy
- Urinary incontinence (inability to retain adequate urine)

#### Uncommon side effect (effects that appear in 1-10 out of 1,000 users):

- Problems with your heartbeat such as slow heartbeat
- Seeing things that are not really there (hallucinations)
- Stomach ulcer
- Dehydration (losing too much fluid)
- Hyperactivity (high level of activity, restlessness)
- Aggression

#### Rare side effect (effects that appear in 1-10 out of 10,000 users):

- Falling

#### Very rare side effect (which appear in less than one out of 10,000 users):

- Stiff arms or legs
- Trembling hands

#### Side effects of unknown frequency (which have not yet been determined):

- Allergic reaction where the patch was used, such as blisters or inflamed skin
- The signs of Parkinson's disease get worse – such as tremor, stiffness and shuffling

- Inflammation of the pancreas – signs include serious upper stomach pain, often with feeling sick (nausea) or being sick (vomiting)
- Fast or uneven heartbeat
- High blood pressure
- Fits (seizures)
- Liver disorders (yellow skin, yellowing of the whites of the eyes, abnormal darkening of the urine or unexplained nausea, vomiting, tiredness and loss of appetite)
- Changes in tests which show how well the liver is working
- Feeling restless
- Nightmares

Take off your patch and tell your doctor straight away, if you notice any of the side effects above.

**Other side effects seen with Rivastigmine capsules or oral solution and which may occur with Rivastigmine Patch Dexcel:**

#### Common side effects (effects which appear in 1-10 out of 100 users):

- Too much saliva
- Loss of appetite
- Feeling restless
- Generally feeling unwell
- Trembling or feeling confused
- Increased sweating

#### Uncommon side effect (effects that appear in 1-10 out of 1,000 users):

- Uneven heart rate (e.g. fast heart rate)
- Difficulty sleeping
- Accidental falls

#### Rare side effect (effects that appear in 1-10 out of 10,000 users):

- Fits (seizures)
- Ulcer in the intestine
- Chest pain (Angina Pectoris)

#### Very rare side effect (which appear in less than one out of 10,000 users):

- High blood pressure
- Inflammation of the pancreas – the signs include serious upper stomach pain, often with feeling sick (nausea) or being sick (vomiting)
- Bleeding in the gut – shows as blood in stools or when being sick
- Seeing things that are not there (hallucinations)
- Some people who have been violently sick have had tearing of the tube that connects your mouth with your stomach (oesophagus)

If you experience a side effect or if one of the side effects worsens or if you suffer from any side effect not listed in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "דיווח על תופעות לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form of adverse events reporting or via the following link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

### 5. How to store the medicine

- **Avoid poisoning!** This medicine, and all other medicines, must be stored in a closed place out of the reach of children and/or infants, to avoid poisoning.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: store at a temperature below 25°C. Store in the original package.
- Keep the transdermal patch in the sachet until use.
- Do not use any patch that is damaged or shows signs of tampering.
- After removing a patch, fold it in half with the sticky sides on the inside and press them together.

Return the used patch to its sachet and dispose of it in such a way that children cannot handle it. Do not touch your eyes with your fingers and wash your hands with soap and water after removing the patch.

### 6. Additional information

#### In addition to the active ingredient, this medicine also contains:

Polyester film, fluoropolymer-coated, Polyethylene/thermoplastic resin/aluminum coated polyester film, Poly [(2-ethylhexyl)acrylate, Vinylacetate], High molecular weight polyisobutene, Paraffin light liquid, Medium molecular weight polyisobutene, Silica colloidal anhydrous, Orange printing color.

#### What the medicine looks like and contents of the pack:

Round patch. The outer layer is light brown and labelled with the following:

"RIV-TDS 4.6 mg/24 h" for **Rivastigmine Patch Dexcel 4.6mg/24h**.

"RIV-TDS 9.5 mg/24 h" for **Rivastigmine Patch Dexcel 9.5mg/24h**.

Each patch is packed in a closed sachet. Each pack contains 30 sachets.

**Manufacturer:** LUYE PHARMA AG, MIESBACH, GERMANY

**This leaflet was checked and approved by the Ministry of Health in: July 2017.**

#### Drug registration numbers at the national medicines registry of the Ministry of Health:

**Rivastigmine Patch Dexcel 4.6mg/24h: 158-87-34462-00**

**Rivastigmine Patch Dexcel 9.5mg/24h: 158-88-34452-00**

Rivastigmine Patch Dexcel PIL PB1017-02

Registration holder: **Dexcel® Ltd.**

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